510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k061503

B. Purpose for Submission:

Modification of an existing product

C. Measurand:

Cyclosporine

D. Type of Test:

Calibrator

E. Applicant:

Dade Behring, Inc.

F. Proprietary and Established Names:

Dimension® Extended Range Cyclosporine Calibrator (DC108A)

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DLJ, Calibrators, Drug specific	Class II	21 CFR §862.3200 Clinical Toxicology Calibrator	Toxicology

H. Intended Use:

1. Intended use(s):

   See below.

2. Indication(s) for use:

   The Dimension® CSAE Cyclosporine Extended Range Calibrator is an *in vitro*

diagnostic product intended to be used to calibrate the CSAE Cyclosporine Extended range method for the Dimension® clinical chemistry system and the Syva® Emit® 2000 Cyclosporine assay.

3. Special conditions for use statement(s):

   None

4. Special instrument requirements:

   Not applicable to a calibrator

I. Device Description:

The Dimension® CSAE Cyclosporine Extended Range Calibrator contains cyclosporine in a preserved whole blood hemolysate. The kit consists of 2 sets of the following: one glass vial of sample diluent (0.0 ng/ml of cyclosporine) and one glass vial of levels 1 through 5. Target concentrations for the five calibrator levels are approximately 200, 400, 800, 1400 and 2000 ng/ml of cyclosporine. Level 0 is included for dilution of over-range samples (>2000 ng/mL) in order to obtain results within the assay range; it is not used in calibration. Levels 1 thru 5 are used for calibration of the CSAE method.

Human Source Material was tested by FDA approved methods for the presence of antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2), as well as for Hepatitis B Surface Antigen and antibody to Hepatitis C Virus (HCV), and found to be negative (not repeatedly reactive.)

A. Substantial Equivalence Information:

Predicate device name(s):

Dimension Cyclosporine Extended Range Calibrator (DC108)

Predicate K number(s):

k052015, k053108

Comparison with predicate:

The Dimension CSAE Cyclosporine Extended Range Calibrator (DC108A) is identical to the predicate in the following ways: intended use, matrix, and target concentrations of calibrators. This device is different to the predicate in the following ways:

Differences		
Item	Device	Predicate
Traceability	Reference lot stock solution prepared gravimetrically. Final reference lot sent out for LC/MS/MS assignment.	Reference lot stock solution tested by LC/MS/MS internally then formulated. Final reference lot sent out for LC/MS/MS assignment.
Value Assignment of new calibrator lot	Stock solution for new calibrator formulated using standard gravimetric procedures prior to formulation.	Stock solution for new calibrator formulated using standard gravimetric procedures and tested by LC/MS/MS prior to formulation.
Production site	Calibrator manufactured by Dade Behring Inc. in Glasgow Delaware.	Calibrator prepared by an OEM Manufacturer for Dade Behring Inc.
Packaging	Glass vials.	Plastic vials.
Storage temperature	Unopened storage temperature is -15 to -25°C.	Unopened storage temperature is -17 to -27°C.

K. Standard/Guidance Document Referenced (if applicable):

STANDARDS
Title and Reference Number
Medical Devices - Symbols to be used with medical device labels, labeling and information to be supplied (15223)
Medical devices - Application of risk management to medical devices (14971:2000)
Stability Testing of In Vitro Diagnostic Reagents (13640)
Continuous Quality Improvement: Essential Management Approaches; Approved Guideline (GP 22-A)

GUIDANCE			
Document Title	**Office**	**Division**	**Web Page**
Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use			**http://www.fda.gov/cdrh/ocd/guidance/4444.html**
Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Guidance for Industry and FDA	**OIVD**	**DCTD**	**http://www.fda.gov/cdrh/ode/guidance/1380.html**

L. Test Principle:

Not applicable.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not applicable.

b. Linearity/assay reportable range:

Not applicable.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Stability:
Target shelf life for the Dimension® CSAE Calibrator (DC108A) is 12 months. Calibrator shelf life is determined by comparing results of the product stored at -15 to -25°C (recommended storage temperature) with product stored at -70°C (reference storage temperature) to ensure that analytical system drift is dissociated with calibrator drift. Three lots of product were tested on days 0, 7, 14, 30, 90, 120, 150, 180, 210, 240, 270, 300, 330, 360, 390.

Traceability:
Commercially available CSA powder is used to formulate a reference stock solution. A reference lot is formulated by diluting the stock into whole blood hemolysate with preservatives at six different levels and stored -70º C. The reference lot value is assigned by LC/MS/MS.

Value Assignment:
A cyclosporine stock solution is prepared using standard gravimetric procedure. Aliquots of the stock solution are added to measured amounts of calibrator matrix to yield the desired concentration for each calibrator level. Cyclosporine calibrators are prepared in preserved whole blood hemolysate. The recovery of the six levels are verified versus a control calibrator lot (control calibrator = any approved calibrator lot) and versus the frozen reference lot.

d. Detection limit:

Not applicable.

e. Analytical specificity:

Not applicable.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable.

b. Matrix comparison:

Not applicable.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

*b. Clinical specificity**:***

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable.

4. Clinical cut-off**:**

   Not applicable.

5. Expected values/Reference range:

   Not applicable.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.